COVID-19 VACCINE BULLETIN 23

Welcome to Bulletin 23 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

Updates and Reminders on the Vaccination Programme

Dose Interval for Vaxzevria® (AstraZeneca) vaccine is reduced to 8 weeks

Recently the National Immunisation Advisory Committee (NIAC) has advised that individuals who have received their first dose of Vaxzevria® should get their second dose 8-12 weeks later (an 8-week interval is preferred). The HSE is working to reduce the time between dose 1 and dose 2 to 8 weeks.

This will take time to reduce everyone's appointment to an 8-week gap.

The interval between the first and second dose can be reduced to between 4 weeks to under 8 weeks if required (e.g. if it allows for the schedule to be completed by 36 completed weeks of pregnancy or for those with planned immunosuppressive therapy to allow for completion of vaccination before treatment).

The interval between the two doses has been reduced for all so that the vaccination schedule can be completed quicker and individuals are better protected against COVID-19 including the delta variant.

Read the updated chapter 5a on COVID-19 vaccines within the immunisation guidelines produced by NIAC

NIAC Chapter

European Medicines Agency (EMA) advises against use of Vaxzevria® in people with history of capillary leak syndrome

On 11/06/2021, the EMA's safety committee (PRAC) concluded that people who have previously had a very rare syndrome called capillary leak syndrome, must not be vaccinated with Vaxzevria® vaccine (AstraZeneca). The Committee also concluded that capillary leak syndrome should be added to the product information as a new side effect of the vaccine, together with a warning to raise awareness among healthcare professionals and patients of this very rare risk.

Capillary leak syndrome is a very rare, serious condition that causes fluid leakage from small blood vessels (capillaries), resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood and low blood levels of albumin.

The Committee carried out an in-depth review of 6 cases of capillary leak syndrome in people who had received Vaxzevria. Most of the cases occurred in women and within 4 days of vaccination. Three of those affected had a history of capillary leak syndrome and one of them subsequently died. This is very rare: as of 27 May 2021, more than 78 million doses of Vaxzevria had been administered in the EU/EEA and the UK, and just 6 cases were identified by the EMA.

The EMA advises that healthcare professionals should be aware of the signs and symptoms of capillary leak syndrome and of its risk of recurrence in people who have previously been diagnosed with the condition.

Healthcare professionals should tell people receiving the vaccine that they must seek medical attention if they have the following symptoms in the days after vaccination, which may be associated with feeling faint (due to low blood pressure):

- oedema in the extremities
- sudden weight gain.

People who have been vaccinated with Vaxzevria should seek immediate medical assistance if they experience rapid swelling of the arms and legs or sudden weight gain in the days following vaccination. These symptoms are often associated with feeling faint (due to low blood pressure).

The PRAC will continue to monitor for cases of the condition and will take any further actions necessary.

Read the Statement

Training and guidance for vaccinators will be updated to include this information.

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Update on the ongoing review by the European Medicines Agency on reports of myocarditis and pericarditis following vaccination with COVID-19 vaccines

The European Medicines Agency is continuing its assessment of a small number of reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) following vaccination with all COVID-19 vaccines. Currently, more information is needed to determine whether or not there is a causal relationship with the vaccines and the EMA is continuing its review.

The EMA encourages all healthcare professionals to report any cases of myocarditis or pericarditis and other adverse events in people having these vaccines. Patients who have symptoms such as shortness of breath, a forceful heartbeat that may be irregular, and chest pain following vaccination should consult their doctor.

Read the EMA Statement

Communicating the importance of completing the vaccine schedule

Health care professionals should be able to communicate the importance of having the second dose of the same vaccine if the vaccine is part of the two dose schedule. In particular there are a number of queries around the second dose of Vaxzevria®.

As recommended by NIAC it is important that everyone receive both doses of Vaxzevria® vaccine (unless there are clinical contraindications) , so that they have the best protection against COVID-19 including against the delta variant of concern (which is spreading rapidly in the United Kingdom). Having a different COVID-19 vaccine from your first dose is not recommended by NIAC as there is currently no data to support how well this protects people against COVID-19. Very rarely 1 in 100,000 people may develop very unusual blood clots with low platelets after vaccination. These blood clots are less likely to be reported after the second dose of the vaccine.

Individuals who have concerns about receiving their second dose of Vaxzevria® are being advised:

- To read more about what they can expect after getting Vaxzevria® vaccine on our Vaxzevria® side effects section.

  Read more here

- They can talk to their vaccinator prior to getting the vaccine and they will be consented before they get their COVID-19 vaccine.

- They should speak to a trusted health care provider like their doctor if they are concerned about getting the second dose of Vaxzevria®.

  Read more here

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Overview of EU/EEA country recommendations on COVID-19 vaccination with Vaxzevria and scoping review of evidence

Twenty member states recently surveyed in the European Union are in line with this advice recommending those who have had a first dose of Vaxzevria® to go on to receive the same vaccine for the second dose.

Read more here

Vaccine doses required for those who have had COVID-19

In addition, NIAC have also recommended that those with a laboratory confirmed COVID-19 infection in the prior 9 months (previous guidance was 6 months) and are under the age of 50 and immunocompetent may receive only 1 dose of a COVID-19 vaccine to be considered fully immunised.

However, the HSE is not currently operationalising this guidance from NIAC. Everyone will be offered two appointments at the appropriate interval for a two dose COVID-19 vaccine regardless of prior COVID-19 infection status.

Read more here

Vaccine Preparation Reminder

A number of enquiries have been received around vaccine preparation. Please read the clinical guidance document for up-to-date advice on correct vaccine dilution (if needed), preparation and administration for each vaccine.

The clinical guidance is based on the summary of product characteristics (SmPC) provided by each of the manufacturers for their products.

For example, for Comirnaty® (Pfizer BioNTech) during dilution the needle should be inserted at a 90 degree angle into the stopper as shown in the summary of product characteristics (section 6.6) and the HSE clinical guidance:

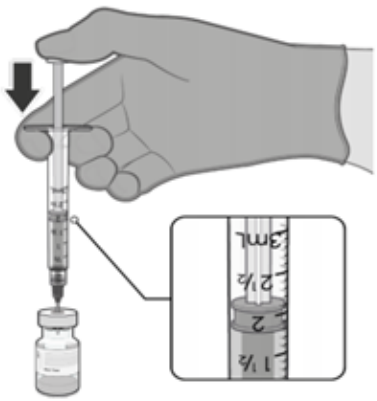

Exhibit 1: Taken from the SmPC for Comirnaty (section 6.6) showing how to add the diluent

Read more here

Read more here

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Risk communication around TTS

A number of queries have been received about how the risk of Thrombosis with Thrombocytopenia Syndrome (TTS) following Vaxzevria® or COVID-19 Vaccine Janssen® is presented in different materials.

In the national immunisation guidelines produced by NIAC the risk of TTS reported is based on actual estimates from data post vaccination in the European Union (for Vaxzevria®) and United States (for COVID-19 Vaccine Janssen®). This has been used in the official HSE leaflets:

- Very rarely there is a 1 in 100,000 risk of TTS post vaccination with Vaxzevria® and
- Very rarely there is a 1 in 300,000 risk of TTS post vaccination with COVID-19 Vaccine Janssen®

However, the product information produced by the manufacturer categorises the risk following a generic standardised definition for the frequency of adverse event. This definition is used for all medicines including vaccines and is as follows:

- Very common is ≥ 1/10
- Common is ≥ 1/100 to < 1/10
- Uncommon is ≥ 1/1 000 to < 1/100
- Rare is ≥ 1/10 000 to < 1/1 000
- Very Rare is < 1/10 000

As the risk of TTS is a very rare risk, it is reported in the standardised format of<1 in 10,000 in the manufacturer's product information leaflets which encompasses the risk published in the NIAC guidance and HSE leaflets.

An adverse event that occurs in 1 in 100,000 or in 1 in 300,000 occurs in fewer than 1:10,000. Both these reports are therefore not inconsistent and it is a different way of reporting.

Read more here

Read the HSE Patient Information Leaflets

Read the Manufacturer Product Information

Update from the National Immunisation Advisory Committee

The RCPI National Immunisation Advisory Committee has issued an updated COVID-19 Chapter 5A for the Immunisation Guidelines for Ireland.

Read more here

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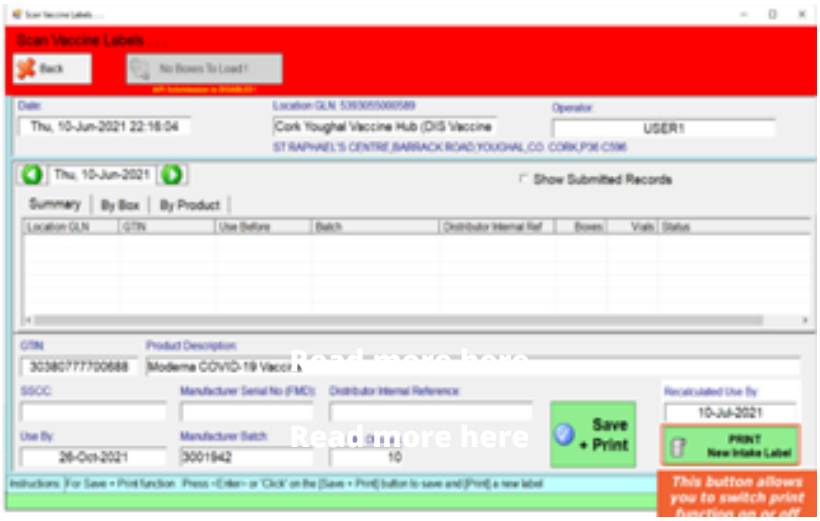
New Scanvax Functionality

Moderna COVID-19 vaccine USE BEFORE Date/Time

Currently the USE BEFORE date and time must be manually recorded on the Moderna COVID-19 vaccine box by adding 30 days from date and time of delivery by National Cold Chain Service.

A new functionality is being rolled out in ScanVax/GS1 and available from Tuesday 15th June.

The new functionality allows that when scanning the Moderna 2D barcode into ScanVax/GS1, then the app will automatically calculate the new USE BEFORE date and time, and will generate a new label.



Where a printer is available, print the label with the new USE BEFORE date/time and apply it on the box. If a printer is not available, manually record the USE BEFORE date and time displayed on the screen onto the box.

For non-CVC sites which require Zebra printers to reprint new labels for Moderna Covid-19 vaccine or other vaccines then please contact HSE National Service Desk at 0818 300 300

- Select option 1 for Covid support
- Ask for Graham Kennedy or Sean O' Malley
- Request a Zebra printer for ScanVax.
- Supply :
  - Tag number of the laptop/desktop that they wish to install the software
  - Eircode location of site with
  - Backup contact number where possible.

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Latest in Research

Investigation of ITP after COVID-19 vaccines

This Scottish study reviews the risk of idiopathic thrombocytopenic purpura (ITP) following vaccination with either a single dose of Vaxzevria® or Comirnaty®. Their estimates suggest a potentially small increased rate of ITP following vaccination with Vaxzevria® around 1.13 in 100,000.

The risk of ITP suggested here is in the context of one study. In comparison COVID-19 itself can cause significant morbidity and mortality. ITP is currently not included as an adverse event for the vaccine in the licensed documentation from the European Medicines Agency. The safety of COVID-19 vaccines is continuously monitored by the EMA, the Health Products Regulatory Authority (HPRA) and NIAC. The benefits from receiving the Vaxzevria vaccine outweigh the risks for adults of all age groups.

Read more here

Antibodies against delta and beta variants of concern after Pfizer BioNTech COVID-19 Vaccine

In this correspondence to the Lancet the authors describe initial analysis from the Legacy Study. The laboratory analysis looks at neutralising antibody activity in participants after one or two doses of the vaccine including against the three variants of concern (B1.617.2, B.1.351 and B.1.1.7.). After two doses of the vaccine neutralising antibodies were found in the serum of most participants against all the strains examined including against the variants of concern. Although there were lower levels of neutralising antibodies against the delta variant (when compared to the original strain or the alpha variant). In addition the authors reports significantly reduced neutralising antibodies against the beta and delta variants in older participants and over time (since the second dose). Furthermore they notice neutralising antibody activity against the beta and delta variants of concern after only one dose is significantly lower in comparison to the alpha variant.

Although this study may imply a lower efficacy for the vaccine against the delta variant you need further real world studies and data to understand the impact on outcomes such as severe COVID-19 and deaths. It further highlights the importance of ensuring individuals receive both doses of the vaccine to get the best protection against variants of concern.

Read more here

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Website

Visit our website www.immunisation.ie regularly for the most up to date information to support vaccinators and health professionals responding to queries.

Our dedicated COVID-19 Vaccination section contains

- Information from the National Immunisation Advisory Committee
- Clinical guidelines
- COVID-19 vaccine studies
- IM Injection technique reminders
- Dedicated pages for the licensed COVID-19 vaccines

Visit here

COVID-19 Vaccination Training Programme

While HSeLand is unavailable you can access the National Immunisation Office COVID-19 vaccinator training by registering through the interim HSeLand solution:

Register here

You must register on this platform to complete training if you previously registered on HSeLand. HSeLand recommend downloading your certificates of completion from the interim HSeLand platform so you can load them to your learning record when HSeLand is available again.

Do you have queries?

Due to a recent cyberattack against the HSE we are unable to access our HSE Emails at this time. We apologise for any inconvenience this may cause.

A new email address for **healthcare professionals only** to direct any urgent clinical or technical queries to. Please **do not send any patient identifiable information** to this email address as the email will be deleted and you will be asked to resend without this information.

Send your query

Should vaccines be exposed to temperatures outside of parameters please contact the National Immunisation Office immediately. Contacts include:

- Achal Gupta: 087 4064810
- Mariangela Toma: mobile 087 7575679
- Cliona Kiersey: mobile 087 9915452

Queries that are not clinical or technical cannot be answered by the National Immunisation Office.

The National Immunisation Office is not involved in the allocation or delivery of COVID-19 Vaccines.

Read about the role of the National Immunisation Office in supporting the COVID-19 vaccination programme on our **website**.

Recommendations about COVID-19 vaccine are changing as more information becomes available so please visit our **website** for the most up to date information.